OBJECTIVE: To optimize the design of a large, complex, proposed trial, and to estimate the power / precision / sample-size / effect-size relationships of that trial, by means of a realistic Monte-Carlo simulation. The proposed trial would evaluate the third-party-payer cost-effectiveness of using standardized combination regimen kits vs. current practice to manage and treat acute sinusitis. Availability of standardized kits could potentially simplify non-prescription product selection, improve adherence, and prevent unnecessary antibiotic prescribing. **METHODS:** Using the R programming language, we simulated all essential operational features of the proposed trial—presentation of patients with bacterial or viral sinusitis, randomization to usual care or one of two standardized kits; effectiveness of the first-round regimen, and prescription (if necessary) of second-round therapy. Using best available literature values for bacterial and viral sinusitis prevalence, distribution of prescription and OTC medication costs, and response rates to various regimens, and using various postulated sample sizes and kit costs, 1000 simulations of each scenario were run. Cost-effectiveness, power, precision, and sensitivity analyses were conducted on the simulated outcomes. **RESULTS:** Empirical models of power as a function of effect size, sample-size, response rates, and kit costs were fitted to the simulation results; these were used to create interactive graphical displays showing the power-vs.-sample-size curves, and precision-of-cost-estimate curves, for any response rate and kit cost. The ease of manipulation of these graphs permitted the rapid exploration of many alternative scenarios, leading to an optimized study design. **CONCLUSIONS:** The simulation analysis of this complex trial permitted not only the reliable estimation of power and precision for a complex study, but also provided a framework for thinking rigorously and quantitatively about the design of the study, and for acquiring and utilizing available data required for the optimization of the study.

IN3

COSTS OF DELIVERING ADULT INFLUENZA VACCINATION IN NON-TRADITIONAL SETTINGS

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OBJECTIVES: To measure the costs of delivering inactivated influenza vaccinations to adults in non-traditional settings. Non-traditional settings may represent an opportunity for boosting influenza immunization coverage rates for recommended adults. **METHODS:** We collected data through telephone surveys with representatives of organizations that conduct mass vaccination clinics for influenza vaccination in a variety of non-traditional settings, such as employer sites, retail stores and pharmacies (n = 7) and pharmacies that use pharmacists to deliver vaccinations (n = 5). Telephone interviews were conducted between January and April, 2004. Data on costs of vaccine dose, supplies, clinical and administrative labor costs, overhead, promotion/advertising, number of vaccinations delivered, and waiting and vaccination time for vaccine recipients were collected. Time costs were calculated using 2003 average US wage data. Primary outcomes were total costs per vaccination delivered including and excluding recipient time costs. **RESULTS:** Survey participants delivered 4.5 million doses of influenza vaccine through mass vaccination clinics and 300,000 doses via pharmacists for the 2003–2004 influenza season. Mean total costs per vaccination, not including time costs, were estimated to be $17.04 (95% CI: $14.43–$19.66) for mass vaccination clinics and $11.57 (95% CI: 9.79–$13.35) for pharmacists. If time costs were included, total vaccination costs were $20.52 (95%CI: $17.38–23.66) for mass vaccination clinics and $15.20 (95%CI: $12.21–18.20) for pharmacists. The largest single component of costs was the cost of the vaccine dose (range = $6.75–$8.95). Mean waiting and vaccination times for the recipient were estimated to be 12 minutes in both settings. **CONCLUSIONS:** Compared to published estimates of delivering influenza vaccination through scheduled visits in the traditional physician office setting of $21.34–$50.43 (Coleman MS et al., 2005), costs of delivering influenza vaccination may be lower in non-traditional settings. Data on costs of vaccination by specific setting type are required for evaluating the cost-effectiveness of delivering influenza vaccination in non-traditional versus traditional settings.

IN4

COST EFFECTIVENESS OF HIV TREATMENT INNOVATIONS OF GREATER EFFICACY THAN HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART)

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OBJECTIVES: We evaluated the long-term clinical benefits and costs associated with HAART from a societal perspective with respect to its current efficacy, and explored the cost-effectiveness of therapies of greater efficacy. **METHODS:** A Monte Carlo Markov model was created to simulate the treatment sequence and disease progression and costs for a hypothetical cohort of 10,000 asymptomatic, treatment-naïve patients initiating HAART with CD4 cell count of 200–350 cells/μL and viral load of 100–55,000 RNA copies/mL. The model's treatment states are two distinct HAART regimens, a rescue regimen, and no antiviral treatment. During each yearly cycle, the patient has either therapeutic success or failure with no AIDS-related infections, AIDS, AIDS-related death, or death from other causes, the probabilities of which (except other cause death) are dependent on CD4 cell count. Model parameters were derived from published literature and data from the Multicenter AIDS Cohort Study. Assuming future treatment strategies improve upon the utility of HAART by increasing the probability of treatment success by at least 10%, we estimate mean costs and quality adjusted life years (QALYs) of HAART and future treatments. **RESULTS:** Mean costs of non-HAART (modeled for comparison), HAART and rescue regimens are $7739, $14,468, and $34,196, respectively. Mean costs of AIDS and AIDS-related death are $28,772 and $67,533, respectively. Mean survival times are 5.19 and 2.55 years (4.01 and 1.92 QALYs) for the HAART and non-HAART cohorts, respectively. Mean discounted (at 3%) lifetime cost of HAART was $171,313. The ICER of HAART over non-HAART was $22,570/QALY. Future treatment strategies of 10% greater efficacy lead to a mean of 0.43 QALYs gained at a cost of $5749 ($13,318/QALY). Future treatment costs <120% of current HAART, have an ICER of <$0,000/QALY. **CONCLUSIONS:** Even modest increases in treatment success and cost result in additional QALYs well below the generally accepted threshold.

Quality of Life

QL1

IS RELIEF WORTH THE RISK? RISK-BENEFIT PREFERENCES FOR TREATMENTS FOR VASOMOTOR SYMPTOMS

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OBJECTIVES: To derive valid estimates of women's willingness to accept elevated fracture, cardio-vascular and cancer risks in return for the benefits of treatments that reduce vasomotor symptoms. **METHODS:** This study used a pretested stated-